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## TITLE PAGE

# Combining electromagnetic navigation and 3-D mapping to reduce fluoroscopy time and achieve optimal CRT response

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Umberto Barbero, MD\*; Carlo Budano, MD; Pier Giorgio Golzio, MD, FESC, FACC;  
Davide Castagno, MD, PhD; Fiorenzo Gaita, MD, Prof.

10 Division of Cardiology, Cardio-Thoracic Department, Azienda Ospedaliero-Universitaria  
Città della Salute e della Scienza di Torino, corso A. M. Dogliotti 14, 10126 Turin, Italy

\* Corresponding author: Umberto Barbero, Division of Cardiology, Cardio-Thoracic  
Department, Azienda Ospedaliero-Universitaria Citta` della Salute e della Scienza di Torino –  
15 Presidio San Giovanni Battista (‘Molinette’), Corso A. M. Dogliotti, 14, 10126 Torino, Italy.  
Tel: + 39 0116636165, +39 3332274241; fax: +39 0116967053. E-mail address: ubarbero@  
unito.it

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## ABSTRACT

Implantation of cardiac resynchronization therapy (CRT) devices can be challenging, time consuming, and associated with high-dose X-Ray exposure. We present the technique in which an electromagnetic navigation system (MediGuide™, St. Jude Medical) and an electro-anatomical three-dimensional mapping system (EnSite NavX, St Jude Medical) are usefully combined for implanting ICD-CRT devices with strong reduction of X-ray exposure, and for targeting the most delayed regions in the activation maps avoiding scars for optimal CRT response.

## Keywords

Cardiac resynchronization therapy; coronary sinus; electro-anatomical mapping; electro-magnetic mapping.

## INTRODUCTION

Implantation of cardiac resynchronization therapy (CRT) devices can be associated with high-dose X-Ray exposure.

5 To reduce that an electromagnetic navigation system (MediGuide™, St. Jude Medical, St. Paul, MN, USA) (MDG) (1) has been developed, displaying real-time location of sensor-embedded tools.

Even after a successful implantation, however, the response to CRT is variable; up to 30%–40% of patients may not show improvement (the so-called “non-responders”).

10 That may be due to different mechanisms, like LV lead deployment over scarred myocardium, or in regions distant from the latest activated ones (2,3).

We present our experience in combining the MDG and an electro-anatomical three-dimensional mapping system (EnSite NavX, St Jude Medical Inc., St. Paul, MN, U SA) (NvX) (4) to strongly improve outcomes of an ICD-CRT implantation through reduction in

15 X-ray exposure and need for dye, and through targeting the most delayed regions in the activation maps avoiding myocardial scars.

## Technical Report

After acquisition of the informed consent, the procedure was performed under local  
 20 anaesthesia and continuous monitoring of invasive blood pressure, electrocardiogram (ECG), and oxygen saturation. First, right ventricular (RV) lead was placed into the right ventricle using conventional fluoroscopy in order to quickly achieve this first target. Then, two ECG-gated X-ray fluoroscopy loops in left anterior oblique (LAO) 40° and right anterior oblique (RAO) 30° views were recorded: these were used as the base interface for real-time catheter  
 25 navigation of the MDG system. The tip of a sensor-equipped, 8F slittable, non-steerable outer catheter (CPS Direct, MediGuide-Enabled, St. Jude Medical Inc.) was 3-D real-time tracked within the electromagnetic field by MDG. A landmark at the superior vena cava was assigned, and the shaft between the tip of the sensor-equipped outer catheter and the landmark was computed and virtually displayed. Inside the outer catheter a decapolar, steerable catheter for  
 30 electrophysiology (Enquiry, St Jude) was placed. Subsequently, the non-fluoroscopic CS cannulation was performed using the short sequences of live fluoroscopy previously recorded in cine-loop to confirm the position of the delivery. Then, an occlusive retrograde CS venogram was obtained in LAO view, and recorded in MDG system (Fig 1, panel A). The ECG-gated cine-loops displaying CS veins served us as anatomy controls to validate 3-D

EAM and in cases of need of MDG catheter/guidewire tracking or of standard fluoroscopy for completion of the procedure.

Subsequently, the patient underwent intra-procedural coronary venous 3-D EAM using NvX (5). A 0.014-inch PTFE insulated guidewire (Vision Wire, Biotronik) was inserted into the coronary sinus and connected to NvX along with the surface ECG. This guidewire has complete PTFE insulation except for 15mm at the distal J-shaped tip and 30mm at the proximal end allowing unipolar sensing and pacing. This guide was moved backwards and forwards into the main coronary sinus and the lateral veins during intrinsic ventricular activation. Local LV unipolar EGMs were recorded at different points throughout the entire CS and venous branches. Local electrical activation time at each of the mapped points was measured in milliseconds from QRS onset on the surface ECG to the peak negative slope on the unipolar intra-cardiac electrogram (EGM). A composite 3-D EAM of the CS and of the only selectable branch was constructed, by superimposing local electrical activation times on the maps using colour coding, indicating early and late areas of LV activation but also displaying the different voltages (fig. 1 C and D).

After the mapping procedure, the LV lead was connected to NvX for real-time visualization and positioned on the latest activated region with adequate voltages, and confirmed by single-shot fluoroscopy (fig. 1, Panel B). Finally, right atrial (RA) lead was placed into the right atrial appendage using NvX and confirmed as above.

Procedure finally lasted 100 min, with only 3.7 min of fluoroscopy and 182 mGy X-Ray exposure (with 2.46  $\mu\text{Gycm}^2$ ). Just 15 mL of intravenous radiopaque contrast were used for a single CS venography. Voltage maps confirmed the presence of scar in lateral zone of the coronary sinus (figure 2) and through activation maps we chose to place the LV lead in the most delayed conduction outside of the scar zone (see figure 2 and video in the web appendix). The guide successfully entered and mapped only one of the lateral branch of the coronary sinus, but the other one was probably located on the scar region. All three leads were successfully implanted. Final pacing/sensing parameters were in the normal range, with ECG tracings showing a typical biventricular stimulation (fig. 2). After 6-months follow up symptoms improved from NYHA class III to NYHA class II. Echocardiography improvement to moderately reduced ejection fraction. These results are still persisting after 1 year.

## Discussion

Looking into the procedural data of published interventional EP procedures performed using the mapping system technology, we can observe that radiation exposure is dramatically reduced without any negative consequences on procedure duration, efficacy, or complication rates compared to conventional cases (6,7). Cardiac resynchronization therapy today is one of the EP procedure that less is taking advantages of such navigation tool, but previous published experiences and the our we are reporting here seem to reflect the ablation success. (5,8-10). Mapping systems help reducing the need for fluoroscopy, and even when not reaching Zero X-ray, they bring its use to very low and acceptable levels. Single fluoroscopy shot or single dye injection become acceptable in order to increase operators' confidence and patient's safety.

Furthermore, coronary venous 3-D EAM using NvX in combination with a mapping guidewire has already been used at the time of CRT implantation to guide LV lead placement to the latest activated region (11-13). This approach especially contributes to optimization of LV lead electrical delay in patients with multiple target veins but also help to go through the coronary venous system without need of fluoroscopy. Combining the two strategies we reduced fluoroscopy use for a CRT implantation to less than a conventional pace-maker implant, maintaining control of the catheters, delivery system or guidewires in each single step of implantation.

In the case we described above, paying the small cost of some minutes of fluoroscopy we gained a triple system of control (MDG system with its familiar radiological views and control of the delivery outer catheter; NaVx with 3D-EAM to assess anatomy but mostly the electrical information on scars and latest activation site; and single fluoroscopy shot to confirm positions) that also give the possibility to study the activation pattern of LV during the implantation and so to choose the best lead location, increasing chances to improve CRT response and patients prognosis (14).

We speculate that in future this kind of approaches combining mapping systems would probably further reduce X-ray use, with a terrific reduction in exposure to the patient and operator, and optimizing of CRT responders. However, both clinicians and interventionist should be aware of these techniques today, in order to offer the best strategy to patients who meet criteria for CRT implantation.

**Conflict of interest:** none declared.

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## FIGURE LEGENDS

### Figure 1

- 5 Panel A. Selective retrograde angiography of the coronary sinus (CS) in the left-anterior oblique (LAO 30°) view. The red rendered shaft of the sensor-equipped 8F outer catheter (CPS Direct, MediGuide-Enabled, St. Jude Medical Inc.) is real-time tracked in the three-dimensional electromagnetic field. It is superimposed on the ECG-gated X-Ray fluoroscopy loop, and displayed within the CS between the landmark for the superior vena cava (large yellow ring) and the tracked tip (thin yellow ring at the tip of the delivery).
- 10 Different lateral branches are showed in the angiography, in the postero-lateral region, as possible target sites.
- Panel B. Final position of the LV lead tip (right), corresponding to the latest activated region in 3-D EAM.
- 15 Panel C: Intra-procedural coronary venous 3-D EAM using EnSite NavX. LAO 30° (left) and Right Anterior Oblique (RAO) 30° views (right). The 0.014-inch PTFE insulated guidewire (Vision Wire, Biotronik) was connected to EnSite NavX and moved within the CS. During intrinsic ventricular rhythm, local electrical activation times at each of the mapped points were registered, so allowing a composite 3-D EAM reconstruction of the CS by colour coding: white denotes the earliest activated regions (before the 50% of the QRS width of 151 ms, therefore 75 ms), and the purple colour indicates the position of the maximum delay of ventricular activation (over 95% of the QRS width, so over 144 ms) and therefore the best final position for the left lead (the latest activation point was 135 ms). All measurements were performed in NavX at a screen speed of 200 mm/s, with a 1-500 Hz bandpass filtered unipolar
- 20 EGM. Incidentally, comparison of angiography and 3-D EAM shows a good correspondence of main CS and its branches. As previously noted, the latest activated region (the purple color in the lateral branch) corresponds to the final position of the quadripolar lead.
- Panel D: Voltage maps with evidence of low values in the first and medium part of the vein, and voltages >10 mV only in the distal branch.

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### Figure 2.

ECG before (left) and after implantation (right), the last showing a prevailing LV activation (QRS axis – 120 degrees, R in V1) and QRS narrowing. The width of QRS before intervention measured with the Precision System was 151 ms.

